AO 106 (Rev. 04/10) Application for a Search Warrant

UNITED STATES DISTRICT COURT

for the

Eastern District of Virginia

In the Matter of the Search of
(Briefly describe the property to be searched or identify the person by name and address)
San Miguel Market, 5900-C Leesburg Pike, Falls Church, Virginia, 22041

Case No. 1:17SW96

APPLICATION FOR A SEARCH WARRANT

I, a federal law enforcement officer or an attorney for the government, request a search warrant and state under penalty of perjury that I have reason to believe that on the following person or property *(identify the person or describe the property to be searched and give its location)*:
San Miguel Market, 5900-C Leesburg Pike, Falls Church, Virginia, 22041 as described in Attachment A (Property to be Searched).

located in the Eastern District of Virginia, there is now concealed *(identify the person or describe the property to be seized)*:
Please see Attachment B (Particular things to be Seized)

The basis for the search under Fed. R. Crim. P. 41(c) is *(check one or more)*:

- ☑ evidence of a crime;
- ☑ contraband, fruits of crime, or other items illegally possessed;
- ☑ property designed for use, intended for use, or used in committing a crime;
- ☐ a person to be arrested or a person who is unlawfully restrained.

The search is related to a violation of:

Code Section	*Offense Description*
21 U.S.C. § 331(i)(3)	Selling counterfeit drugs;
21 U.S.C. § 331(c)	Receiving misbranded drugs in interstate commerce and offering them for pay;
21 U.S.C. § 331(k)	Causing drugs to become misbranded after they moved in interstate commerce.

The application is based on these facts:
See attached affidavit.

- ☑ Continued on the attached sheet.
- ☐ Delayed notice of _____ days (give exact ending date if more than 30 days: _____) is requested under 18 U.S.C. § 3103a, the basis of which is set forth on the attached sheet.

Applicant's signature

Sean C. Sweeney, Special Agent, FDA
Printed name and title

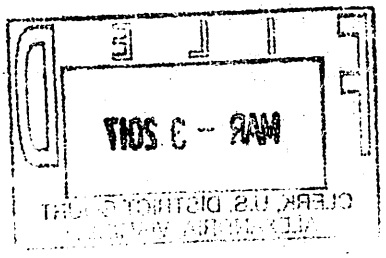
Reviewed by AUSA/SAUSA
William Sloan/ Lauren Archer

Sworn to before me and signed in my presence.

Date: 3 Mar 17

City and state: Alexandria, Virginia

/s/
Ivan D. Davis
United States Magistrate Judge


FILED
MAR - 3 2017
CLERK U.S. DISTRICT COURT

ATTACHMENT A

PROPERTY TO BE SEARCHED

San Miguel Market, located at 5900-C Leesburg Pike, Falls Church, Virginia, 22041, is identified as a business located in a strip mall. There is a glass door and window on the front of the white building and a sign that says San Miguel Market in red lettering above the windows. (See Photo Below)

ATTACHMENT B

ITEMS TO BE SEIZED

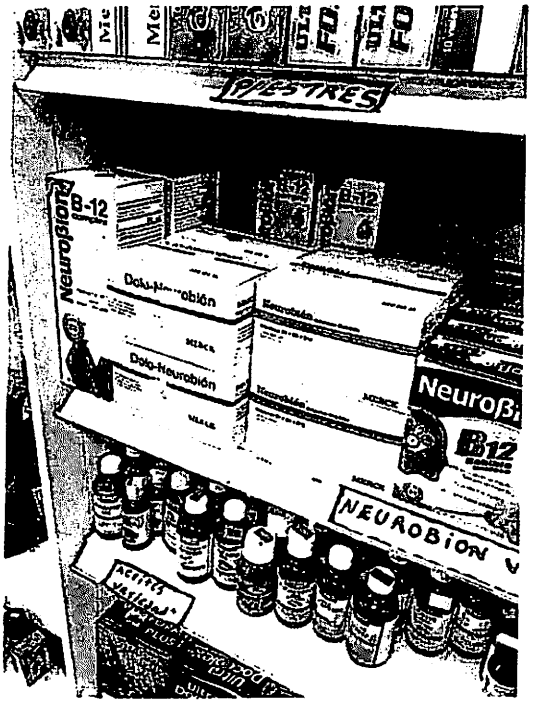
A. Unapproved drugs, misbranded drugs, counterfeit drugs, and prescription drugs, including but not limited to Dolo-Neurobión and Neurobión;

B. Packaging materials printed in Spanish that may contain or have contained unapproved drugs, misbranded drugs, counterfeit drugs, or prescription drugs; and

C. All business records and related correspondence, in whatever form, including handwritten and computer generated, pertaining to the illegal purchase, possession, and unauthorized distribution of unapproved, misbranded and, counterfeit drugs. The documents to be seized are to include those relating to the brokering, ordering, production, purchasing, shipping, sale and distribution of unapproved, misbranded, and counterfeit drugs, including but not limited to business journals and ledgers; and purchase orders; invoices; contracts; receipts; delivery receipts; work orders; telephone, telefax, computer internet records; written and electronic correspondence; bank records, including bank statements; letters of credit; canceled checks; check registers; and other records reflecting payments; airway bills; bills of lading; handwritten notes; memoranda; address books; sales orders; purchase orders; rolodexes; business cards; and other documents identifying suppliers and customers, customer and business contracts; shippers letters of instructions; business inquiries; confirmations; commodity business brochures; supplier and customer lists; records of purchase from suppliers, application forms, documents and literature regarding the FDA and the State of Virginia, information pertaining to the distribution or use of prescription drugs, licenses and/or permits regarding the sale of prescription drugs or pharmacy authorizations.

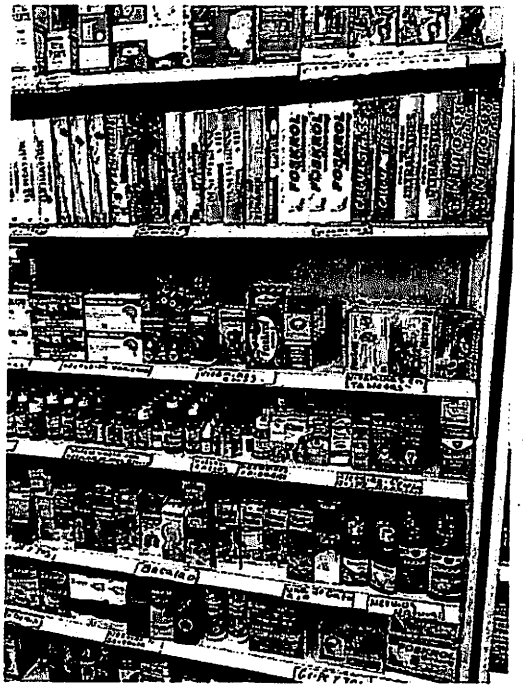
ATTACHMENT C-1

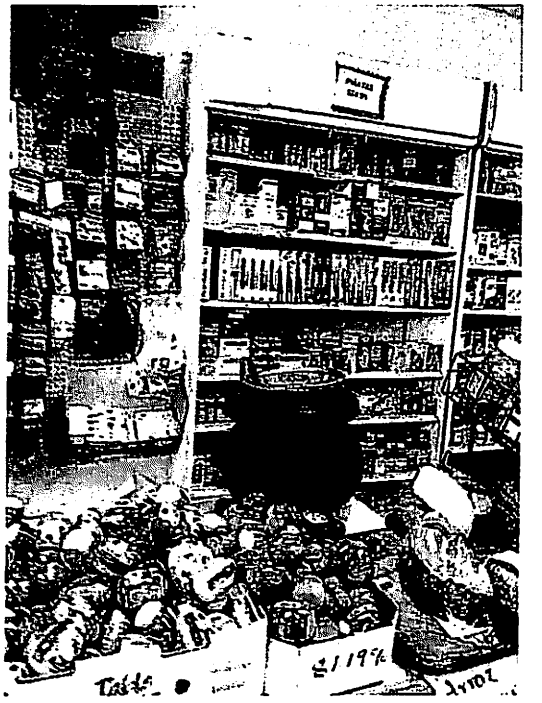
ATTACHMENT C-2



ATTACHMENT C-3

ATTACHMENT C-4





IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

IN THE MATTER OF THE APPLICATION OF THE UNITED STATES OF AMERICA FOR A SEARCH WARRANT FOR SAN MIGUEL MARKET, 5900-C LEESBURG PIKE, FALLS CHURCH, VIRGINIA 22041	)	Case No. 1:17-sw-96

AFFIDAVIT IN SUPPORT OF SEARCH WARRANT

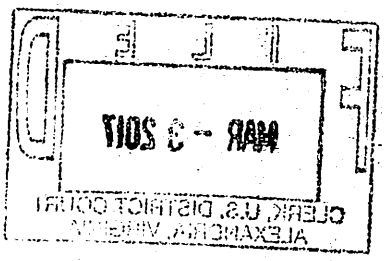
I, Sean C. Sweeney, being duly sworn, depose and state:

INTRODUCTION

1. I am a Special Agent of the United States Food and Drug Administration (FDA), Office of Criminal Investigation (OCI), assigned to the Metro Washington Field Office in Beltsville, Maryland, and have been so employed since February 2002. As such, I am authorized to conduct criminal investigations, make arrests, and execute search and arrests warrants for offenses in violation of the Federal Food, Drug, and Cosmetic Act (FDCA), Title 21, U.S.C. §301, *et seq.* and related violations of Title 18 of the United States Code.

2. Prior to my employment with the FDA-OCI, I was a Special Agent with the FDA's Office of Internal Affairs (OIA) for over two years. Prior to my employment with FDA-OIA, I was a Special Agent with the United States Customs Service for two years. Prior to my employment with the U.S. Customs Service, I was a Special Agent with the United States Naval Criminal Investigative Service for over five years.

3. This investigation is being conducted by FDA-OCI. The information and observations contained herein are known by your affiant personally or has been provided to your affiant by others.


MAR - 3 2017
CLERK, U.S. DISTRICT COURT
ALEXANDRIA, VIRGINIA

SUMMARY

4. This affidavit is submitted in support of a search warrant for San Miguel Market, 5900-C Leesburg Pike, Falls Church, Virginia, 22041 (hereinafter "San Miguel Market" or "TARGET LOCATION") for: (1) selling counterfeit drugs, in violation of 21 U.S.C. § 331(i)(3); (2) receiving misbranded drugs in interstate commerce and offering them for pay or otherwise, in violation of 21 U.S.C. § 331(c); and (3) causing drugs to become misbranded after they moved in interstate commerce and while they were held for sale by dispensing prescription drugs without the valid prescription of a licensed medical practitioner, in violation of 21 U.S.C. §§ 331(k), 353(b)(1), and 333(a)(1).

LEGAL BACKGROUND

5. The FDA is the agency of the United States responsible for, among other things, protecting the health and safety of the American public by enforcing the FDCA. The FDA's responsibilities under the FDCA include regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce.

6. The FDCA defines "drug," in relevant part, as (1) any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (2) articles (other than food) intended to affect the structure and function of the body of humans or other animals; (3) and articles intended for use as a component of any such articles. 21 U.S.C. § 321(g)(1).

7. The FDCA defines a "prescription drug" as any drug intended for use by man which, because of its toxicity or other potential for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe to use except under the supervision of a

practitioner licensed by law to administer such drug; or a drug which was limited by an approved new drug application to use under the professional supervision of a practitioner licensed by law to administer such drug. 21 U.S.C. § 353(b)(1).

8. The FDCA defines many ways a drug could be deemed misbranded. 21 U.S.C. § 352. Many, though not all, of these misbranding violations occur when there is a deficiency in a drug's label or labelling. For example, all drugs in package form are required to bear a label that lists the name and place of business of the manufacturer, packer, or distributor, as well as an accurate statement of the contents in terms of weight, measure, or numerical count. 21 U.S.C. § 352(b). All drugs also must have a label that bears the established name of each active and inactive ingredient. 21 U.S.C. § 352(e). The regulations also mandate that certain information be on the label. For example, a drug's label must contain a lot number capable of tracing the complete manufacturing history of the product, as well as an expiration date supported by stability studies. 21 C.F.R.§§ 201.18, 201.17, 211.137. These requirements ensure that FDA knows who to contact in case there is an issue with the drug, and also that consumers will know what is in a product in case there are adverse events or if an ingredient is contraindicated with other drugs the consumer may be taking. It is not enough that this and other required information is somewhere on the label or labeling; the FDCA requires that the information be placed prominently and with such conspicuousness and in such terms as to render it likely to be understood by ordinary individuals under customary conditions of purchase and use. 21 U.S.C. § 352(c). With some exceptions not relevant here, the information required on labels and labeling by, or under, the authority of the FDCA shall appear thereon in the English language. 21 C.F.R. § 201.15(c)(1). If any of the information on the label or labeling is false or misleading in any particular, the drug also will be deemed misbranded under 21 U.S.C. § 352(a).

9. A drug is also deemed misbranded if its labeling fails to bear adequate directions for use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" is defined as "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. Adequate directions for lay use cannot be written for a prescription drug because such drugs, by definition, can only be used safely at the direction, and under the supervision, of a licensed practitioner. 21 U.S.C. § 353(b).

10. Therefore, in order for a prescription drug to be distributed in interstate commerce, it must qualify for an exemption to this requirement, and 21 U.S.C § 352(f) directs that the Secretary of Health and Human Services promulgate regulations allowing for such exemptions. A prescription drug is exempt from the requirement that its labeling bear adequate directions for lay use if all enumerated conditions are met, including that the drug is: (1) in the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or (2) in the possession of a retail hospital, or clinical pharmacy; or (3) in the possession of a practitioner licensed by law to administer or prescribe such drugs; and the drug is to be dispensed according to a valid prescription from such licensed medical practitioner. The prescription drug must also bear the statement "RX only." 21 CFR §§ 201.100(a)(b), 201.16. The failure of a prescription drug to have the inscription "RX only" on its label at any time prior to dispensing also causes the drug to be deemed misbranded. 21 U.S.C. § 353(b)(4).

11. In addition to the regulatory exemption to the requirement that labeling bear adequate directions for use described above, there is also an exemption in the FDCA that directs that prescription drugs need not comply with certain requirements of the FDCA – including the requirement that labeling bear adequate directions for lay use – if they are dispensed pursuant to

a valid prescription of a practitioner licensed by law to administer such drugs. The dispensing of any prescription drug without the valid prescription of a licensed practitioner is an act that results in the drug being misbranded while being held for sale. 21 U.S.C. § 353(b)(1).

12. The FDCA prohibits, among other things, the following acts related to misbranded drugs:

a. The receipt in interstate commerce of any drug that is misbranded and the delivery or proffered delivery thereof for pay or otherwise. 21 U.S.C. § 331(c);

b. The doing of any act that causes a drug to become misbranded after it has moved in interstate commerce and while it is held for sale (whether or not the first sale). 21 U.S.C. § 331(k).

13. It is also a prohibited act to sell or dispense, or hold for sale or dispensing, a counterfeit drug. 21 U.S.C. § 331(i)(3). A counterfeit drug is a drug which, or the container or labeling of which, without authorization bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, packed, or distributed such drug and which therefore falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor. 21 U.S.C. § 321(g)(2).

GENERAL DRUG INFORMATION

14. Neurobión is the trade name for a drug product that generally contains a mix of B vitamins (B1, B6, B12). Merck and EMD/Serono distribute these products in Latin American countries in various formulations, to include injectables, tablets, soft gel capsules and hard gel

capsules. Merck and EMD/Serono do not manufacture a drinkable formulation, nor do they distribute or have approvals to distribute any of these products in the United States. These products are sold both via prescription and over-the-counter (OTC), depending on the country and the dosage. Generally speaking, high doses intended to treat acute vitamin deficiencies are often in injectable or tablet form and are sold as prescription only in many countries. Medium doses used to maintain vitamin levels are sold as OTC, although it varies by country. Low doses intended to prevent deficiencies from developing are often sold as a dietary supplement, or as OTC drugs. There are similar drug products approved in the United States. For example, I searched FDA's publicly available database "Drugs@FDA" for the active ingredient cyanocobalamin (the established or scientific name for vitamin B12) and found 33 different approved drug products from many different manufacturers. Notably, the injectable products were prescription only, and Neurobión is not approved in the United States, as noted above.

15. Dolo-Neurobión is the trade name of a drug product manufactured by Merck that is similar to Neurobión but also contains a non-steroidal anti-inflammatory (NSAID) called diclofenac sodium, which is used to treat mild to moderate pain, or signs and symptoms of osteoarthritis or rheumatoid arthritis. Diclofenac sodium is only available by prescription in the United States, but in some countries a lower dose 25mg tablet is available OTC. Diclofenac sodium is approved in the United States under various brand names, but Merck's Dolo-Neurobión is not approved.

PROBABLE CAUSE

16. Since in or around October 2011, FDA-OCI, Fairfax County Police Department, Arlington County Police Department, and the U.S. Customs and Border Patrol have been

conducting an investigation into misbranded drugs, including misbranded prescription drugs, sold by supermarkets and convenience stores in Fairfax and Arlington Counties, Virginia, both within the Eastern District of Virginia.

17. Since in or around August 2015, your Affiant has been investigating the San Miguel Market, located at 5900-C Leesburg Pike, Falls Church, Virginia, 22041, in Fairfax County, within the Eastern District of Virginia.

18. According to public records, the San Miguel Market is owned by DINORA ISOLINA RIVAS ("RIVAS"). In 2013, RIVAS was convicted of dispensing prescription drugs from the San Miguel Market without a valid prescription, in violation of 21 U.S.C. § 331(k). During an interview with a law enforcement officer regarding that case, RIVAS stated that she controlled all sales of prescription drugs at the San Miguel Market, and that she knew she was not supposed to sell the drugs. These products included antibiotics, oral contraceptives and other prescription drugs. On February 12, 2013, RIVAS pled guilty and was sentenced to six months of supervised probation with the special condition that she not import or distribute any prescription drugs. *United States v. Dinora Isolina Rivas*, No. 1:12-MJ-653, ECF. No. 21.

19. San Miguel Market is not a licensed pharmacy in the Commonwealth of Virginia nor is RIVAS licensed by the Virginia Department of Health Professionals to prescribe or dispense prescription drugs.

20. On or about December 3, 2015, your affiant went into the TARGET LOCATION and observed Neurobión and Dolo-Neurobión available for sale on the shelves. *See* Attachment C-1. Your affiant used an undercover credit card and purchased for $18.65 one box of Neurobión "vials bebibles" – or drinkable product. I was not asked for nor did I provide a prescription,

although the box did say in Spanish that a prescription was required. Merck's logo was on the box, but there was no listed address, as required. As noted above, Merck does not manufacturer a drinkable form of this product and the product was, therefore, counterfeit. The analysis of the product performed by FDA's Forensic Chemistry Center determined that although Vitamin B12 (cyanobalamin) was listed as an ingredient on the product label, it was not present in the product. Additionally, the product contained quinine and/or quinidine (a non-FDA-approved drug) which was not listed on the product label. The product was thus misbranded under 21 U.S.C. 352(a) for having a false and misleading label, as well as 21 U.S.C. § 352(e) for not listing the ingredients. The labels were also not in the English language as required by 21 U.S.C. 352(c) and 21 C.F.R. § 201.15.

21. On or about August 4, 2016, your affiant went into the TARGET LOCATION and observed at least eight different types (as determined by labeling differences) of Neurobión and Dolo-Neurobión available for sale on the open shelves. *See* Attachment C-2. All the boxes were a bit different, with different fonts, colors and artwork. Your affiant purchased one box of Merck Neurobión "ampollas bebibles" (drinkables) for $20.77. The FDA Forensic Chemistry Center's analysis determined that the ingredients listed on the label were consistent with the ingredients in the product. I emailed photographs of the products to Richard Feldman, Vice President, Trade & Product Safety, EMD Serono (affiliated with Merck), and he opined that all the purported Neurobión products were counterfeit because the logo used on the boxes was discontinued in 2002. He also confirmed that the product could not be authentic as Merck did not manufacture a drinkable version of Neurobión. The product was thus counterfeit. The product was also misbranded because the label did not list the addresses of any manufacturer, did not contain the symbol "Rx only" (though it did note in Spanish that it was a prescription

product), and was not in the English language. Your affiant noted that the labels on the vials were of poor quality – the colors were not vibrant and actually bled, as if they were produced on a home printer. Mr. Feldman also noted that the Dolo-Neurobión shown in the photographs advertised that it contained Diclofenac, which is also a prescription drug.

22. On or about August 24, 2016, your affiant went into the TARGET LOCATION and observed Neurobión on the shelves, but the drinkable Dolo-Neurobión observed on August 4, 2016 was not present. *See* Attachment C-3. The cashier stated there were no boxes of drinkable Dolo-Neurobión in stock but offered Dolo-Neurobión pills as individual-sale blister packs. He pointed to them prominently displayed in the box on the wall behind the counter above eye-level. Your affiant purchased the complete box -- including the package insert -- for $68.50. The package insert explained all the adverse events and contraindications, including that the drug not be taken by someone who has a gastric and duodenal ulcer or people who take diuretics, lithium, and anti-hypertensive drugs. Although "Prescription Only" is written on the box, your affiant was not asked for a prescription. On August 24, 2015, your affiant forwarded photos of the drugs to Richard Feldman, Vice President, Trade & Product Safety, EMD Serono, and he stated the product appeared to be genuine, but was diverted from its intended supply chain. The FDA Forensic Chemistry Center's analysis of the product confirmed that the label was consistent with the ingredients. The label on the box stated that the product was manufactured in Mexico, a fact confirmed by Mr. Feldman. The box also had a lot number and expiration date, which I did not observe on the labels from the earlier purchases on December 3, 2015 or August 4, 2016 (described in paragraphs 20 and 21, respectively).

23. On or about November 14, 2016, your affiant went to the TARGET LOCATION and observed various Neurobión products available for sale, but no drinkable Dolo-Neurobión. The

clerk stated there was no Dolo-Neurobión in stock but the "Neurobión 50 mil" drinkables contained diclofenac (a prescription-only drug). Your affiant purchased a box of "Neurobión 50 mil" drinkables without a prescription for $22.26. This box of Neurobión had different labeling than the other boxes previously purchased by your affiant on December 3, 2015, August 4, 2016, or August 24, 2016 (described in paragraphs 20, 21, and 22, respectively). It listed the ingredients as Vitamin B1, B6 and B12 and lidocaine. The label on the outer carton identified the product as being manufactured in Mexico and bore a lot number and expiration date. The label on the individual vials or ampules, however, had the same expiration date but a different lot number than that on the outer carton. The labeling on the individual ampules – even within the same lot – was different in that the colors were not uniform. The labels also looked like they were carelessly applied. The FDA Forensic Chemistry Center analyzed the product and determined that it did contain diclofenac, although this active ingredient was not listed on the label (and this ingredient is usually not present in the Neurobión product). Moreover, Vitamin B-12 was listed as an ingredient on the label but the lab did not find it in the product. Thus, this product was misbranded for having a false and misleading label, not listing all the ingredients, and for not bearing the "Rx only" symbol. In addition, it was misbranded for being dispensed without a valid prescription, and was counterfeit.

24. On or about January 18, 2016, your affiant went to the TARGET LOCATION and observed Neurobión available for sale on the open shelves. *See* Attachment C-4. Your affiant purchased a box of "Neurobión 50 mil" drinkables and a box of "Neurotropas-DB" for $46.21. The Neurobión 50 mil listed the ingredients as vitamins B1, B6 and B12 and had a lot number and expiration date on the outer carton that did not match the lot number and expiration date on the individual plastic bottles. The analysis of the FDA Forensic Chemistry Center showed that

the product did not contain any of the listed vitamins, but did contain diclofenac, which was not on the label. This product was hence misbranded for having a false and misleading label, not listing all the ingredients, and for being a prescription drug dispensed without a valid prescription. It also was counterfeit.

25. Based on your affiant's investigative background and education, distributors of misbranded drugs at a legitimate business will often maintain books, records, receipts, notes, ledgers, diaries and other papers relating to the transportation, ordering, sale and distribution of these misbranded drugs. Based upon your affiant's investigative background and education, it is believed that San Miguel Market keeps proof of its illegal activities at 5900-C Leesburg Pike, Falls Church, Virginia, 22041, and operates a substantial portion (if not all) of its business from 5900-C Leesburg Pike, Falls Church, Virginia, 22041. Your affiant has not been able to determine through surveillance, business records, or any other method, another location where records and evidence might be stored.

CONCLUSION

26. Based on your affiant's training and experience and the facts set forth in this affidavit, there is probable cause to believe that evidence related to the illegal distribution of counterfeit and misbranded drugs are located within the premises located at 5900-C Leesburg Pike, Falls Church, Virginia, 22041.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Sean C. Sweeney
Special Agent
U.S. Food and Drug Administration
Office of Criminal Investigation

Subscribed and sworn to before me this 3rd day of March 2017.

/s/
Ivan D. Davis
United States Magistrate Judge

ATTACHMENT A

PROPERTY TO BE SEARCHED

San Miguel Market, located at 5900-C Leesburg Pike, Falls Church, Virginia, 22041, is identified as a business located in a strip mall. There is a glass door and window on the front of the white building and a sign that says San Miguel Market in red lettering above the windows. (See Photo Below)

ATTACHMENT B

ITEMS TO BE SEIZED

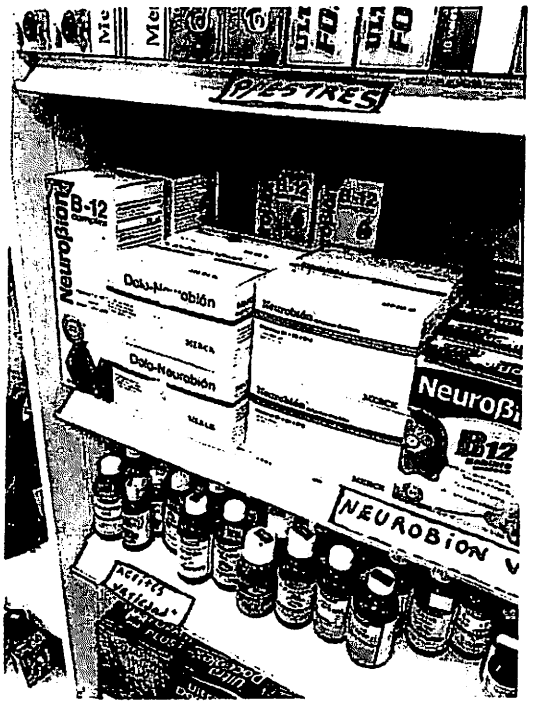
A. Unapproved drugs, misbranded drugs, counterfeit drugs, and prescription drugs, including but not limited to Dolo-Neurobión and Neurobión;

B. Packaging materials printed in Spanish that may contain or have contained unapproved drugs, misbranded drugs, counterfeit drugs, or prescription drugs; and

C. All business records and related correspondence, in whatever form, including handwritten and computer generated, pertaining to the illegal purchase, possession, and unauthorized distribution of unapproved, misbranded and, counterfeit drugs. The documents to be seized are to include those relating to the brokering, ordering, production, purchasing, shipping, sale and distribution of unapproved, misbranded, and counterfeit drugs, including but not limited to business journals and ledgers; and purchase orders; invoices; contracts; receipts; delivery receipts; work orders; telephone, telefax, computer internet records; written and electronic correspondence; bank records, including bank statements; letters of credit; canceled checks; check registers; and other records reflecting payments; airway bills; bills of lading; handwritten notes; memoranda; address books; sales orders; purchase orders; rolodexes; business cards; and other documents identifying suppliers and customers, customer and business contracts; shippers letters of instructions; business inquiries; confirmations; commodity business brochures; supplier and customer lists; records of purchase from suppliers, application forms, documents and literature regarding the FDA and the State of Virginia, information pertaining to the distribution or use of prescription drugs, licenses and/or permits regarding the sale of prescription drugs or pharmacy authorizations.

ATTACHMENT C-1

ATTACHMENT C-2



ATTACHMENT C-3

ATTACHMENT C-4